



INFORMATION DISCLOSURE STATEMENT	ATTY. DOCKET NO. 1530.0460002/EJH/JAH	APPLICATION NO. 10/658,688
	FIRST NAMED INVENTOR Hemanson, G.G.	
	FILING DATE September 10, 2003	ART UNIT 1632

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EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
AS	AA1 4,683,195	07/28/1987	Mullis <i>et al.</i>			02/07/1986
	AB1 5,264,618	11/23/1993	Felgner <i>et al.</i>			04/16/1991
	AC1 5,389,540	02/14/1995	Makoff <i>et al.</i>			11/27/1990
	AD1 5,443,966	08/22/1995	Fairweather <i>et al.</i>			08/23/1993
	AE1 5,459,127	10/17/1995	Felgner <i>et al.</i>			09/16/1993
	AF1 5,571,694	11/05/1996	Makoff <i>et al.</i>			07/25/1994
	AG1 5,580,859	12/03/1996	Felgner <i>et al.</i>			03/18/1994
	AH1 5,591,631	01/07/1997	Leppla <i>et al.</i>			02/12/1993
	AI1 5,643,578	07/01/1997	Robinson <i>et al.</i>			01/27/1993
AS	AJ1 5,677,274	10/14/1997	Leppla <i>et al.</i>			06/25/1993
AS	AK1 5,747,028	05/05/1998	Calderwood <i>et al.</i>			06/07/1995

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EXAMINER INITIAL	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
AS	AL1 CA 2,001,508	04/25/1990	Canada			Yes
AS	AM1 EP 0 366 550 A1	05/02/1990	Europe			X No
AS	AN1 WO 90/04637 A1	05/03/1990	WIPO			Yes
AS	AO1 WO 94/18332 A2	08/18/1994	WIPO			X No
AS	AP1 WO 94/19482 A1	09/01/1994	WIPO			Yes

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

AS	AR	1	Agrawal, A., <i>et al.</i> , "Impairment of dendritic cells and adaptive immunity by anthrax lethal toxin," <i>Nature</i> 424:329-334, Nature Publishing Group (July 2003)
AS	AS	1	Aihara, H. and Miyazaki, J-I., "Gene transfer into muscle by electroporation in vivo," <i>Nat. Biotechnol.</i> 16:867-870, Nature America Publishing (1998)
AS	AT	1	Anderson, R., <i>et al.</i> , "Immunization of mice with DNA encoding fragment C of tetanus toxin," <i>Vaccine</i> 15:827-829, Elsevier (1997)

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AS	AA2	5,837,693	11/17/1998	German <i>et al.</i>			03/24/1995
	AB2	5,840,312	11/24/1998	Mock <i>et al.</i>			10/19/1994
	AC2	5,861,397	01/19/1999	Wheeler			10/03/1996
	AD2	5,994,317	11/30/1999	Wheeler			04/09/1996
	AE2	6,004,944	12/21/1999	Rothman <i>et al.</i>			10/02/1997
	AF2	6,022,874	02/08/2000	Wheeler			12/23/1998
	AG2	6,224,870	05/01/2001	Segal			01/15/1998
	AH2	6,267,966 B1	07/31/2001	Baillie			08/26/1997
	AI2	6,316,006 B1	11/13/2001	Worsham <i>et al.</i>			11/23/1994
↓	AJ2	6,387,665 B1	05/14/2002	Ivins <i>et al.</i>			03/07/2000
AS	AK2	6,379,966 B2	04/30/2002	Monahan <i>et al.</i>			11/29/1999

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AS	AL2	WO 98/08952 A1	05/05/1998	WIPO			Yes
AS	AM2	WO 98/11914 A1	03/26/1998	WIPO			No
AS	AN2	CA 2,202,322	06/20/1998	Canada			Yes
AS	AO2	WO 00/02522 A2	01/20/2000	WIPO			No
AS	AP2	WO 00/02591 A1	01/20/2000	WIPO			Yes
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AS	AR	2	André, S., <i>et al.</i> , "Increased Immune Response Elicited by DNA Vaccination with a Synthetic gp120 Sequence with Optimized Codon Usage," <i>J. Virol.</i> 72:1497-1503, American Society for Microbiology (1998)
AS	AS	2	Darquet, A.-M., <i>et al.</i> , "A new vehicle for nonviral gene delivery: supercoiled minicircle," <i>Gene Ther.</i> 4:1341-1349, Stockton Press (1997)
AS	AT	2	Davis, H.L., <i>et al.</i> , "Direct gene transfer in skeletal muscle: plasmid DNA-based immunization against the hepatitis B virus surface antigen," <i>Vaccine</i> 12:1503-1509, Elsevier Science (1994)

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AS	AA3	6,586,409 B1	07/01/2003	Wheeler			03/24/2000
	AB3	6,632,436	10/14/2003	Segal			02/21/2001
	AC3	6,670,332 B1	12/30/2003	Wheeler			06/05/1998
	AD3	6,696,424 B1	02/24/2004	Wheeler			05/26/2000
	AE3	5,589,466	12/31/1996	Felgner <i>et al.</i>			01/26/1995
	AF3	6,214,804 B1	04/10/2001	Felgner <i>et al.</i>			06/07/1995
	AG3	5,703,055	12/30/1997	Felgner <i>et al.</i>			01/26/1994
	AH3	6,710,035 B2	03/23/2004	Felgner <i>et al.</i>			12/02/1999
	AI3	2001/0031264 A1	10/18/2001	Segal			02/21/2001
↓	AJ3	2002/0019358 A1	02/14/2002	Manthorpe <i>et al.</i>			04/23/2001
AS	AK3	2002/0045594 A1	04/18/2002	Volkin <i>et al.</i>			09/12/2001

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AS	AL3	WO 00/56282 A1	09/28/2000	WIPO			Yes
AS	AM3	WO 00/57917 A2	10/05/2000	WIPO			No
AS	AN3	WO 01/19395 A1	03/22/2001	WIPO			Yes
AS	AO3	WO 01/34801 A2	05/17/2001	WIPO			X No
AS	AP3	WO 01/45639 A2	06/28/2001	WIPO			Yes
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AS	AR	3	Deml, L., <i>et al.</i> , "Multiple Effects of Codon Usage Optimization on Expression and Immunogenicity of DNA Candidate Vaccines Encoding the Human Immunodeficiency Virus Type 1 Gag Protein," <i>J. Virol.</i> 75:10991-11001, American Society for Microbiology (November 2001)
AS	AS	3	Donnelly, J.J., <i>et al.</i> , "DNA Vaccines," <i>Annu. Rev. Immunol.</i> 15:617-648, Annual Reviews Inc. (1997)
AS	AT	3	Duesbery, N.S., <i>et al.</i> , "Proteolytic Inactivation of MAP-Kinase-Kinase by Anthrax Lethal Factor," <i>Science</i> 280:734-737, American Association for the Advancement of Science (1998)

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AS	AA4	2002/0048590 A1	04/25/2002	Klimpel <i>et al.</i>			05/09/2001
	AB4	2002/0051791 A1	05/02/2002	Galloway <i>et al.</i>			12/21/2000
	AC4	2002/0081317 A1	06/27/2002	Mahan <i>et al.</i>			08/09/2001
	AD4	2002/0102277 A1	08/01/2002	Sokol <i>et al.</i>			11/16/2001
	AE4	2002/0142002 A1	10/03/2002	Galloway <i>et al.</i>			03/25/2002
	AF4	2002/0165183 A1	11/07/2002	Herweijer <i>et al.</i>			11/13/2001
	AG4	2002/0197272 A1	12/26/2002	Galloway <i>et al.</i>			03/25/2002
	AH4	2003/0003109 A1	01/02/2003	Galloway <i>et al.</i>			03/25/2002
	AI4	2004/0157789 A1	08/12/2004	Geall			12/02/2003
↓	AJ4	2004/0023911 A1	02/05/2004	Felgner <i>et al.</i>			03/14/2003
AS	AK4	2003/0032615 A1	02/13/2003	Felgner <i>et al.</i>			07/26/2002

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AS	AL4	WO 02/00844 A2	01/03/2002	WIPO			Yes No
	AM4	GB 2,370,772 A	07/10/2002	Great Britain			Yes No
	AN4	WO 04/024067 A2	03/25/2004	WIPO			Yes No
↓	AO						Yes No
AS	AP						Yes No

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AS	AR	4	Felgner, P.L., <i>et al.</i> , "Lipofection: A highly efficient, lipid-mediated DNA-transfection procedure," <i>Proc. Natl. Acad. Sci. USA</i> 84:7413-7417, National Academy of Sciences (1987)
AS	AS	4	Gao, X. and Huang, L., "Potentiation of Cationic Liposome-Mediated Gene Delivery by Polycations," <i>Biochem.</i> 35:1027-1036, American Chemical Society (1996)
AS	AT	4	Gordon, V.M., <i>et al.</i> , "Proteolytic Activation of Bacterial Toxins by Eukaryotic Cells Is Performed by Furin and by Additional Cellular Proteases," <i>Infection & Immunity</i> 63:82-87, American Society for Microbiology (1995)

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AS	AA5	2004/0157244 A1	08/12/2004	Budahazi <i>et al.</i>			11/24/2003
AS	AB5	2004/0162256 A1	08/19/2004	Geall <i>et al.</i>			12/02/2003
AS	AC5	2003/0191082 A1	10/09/2003	Wheeler			03/19/2003
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	AM						No
	AN						Yes
	AO						No
	AP						Yes
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AS	AR	5	Gramzinski, R.A., <i>et al.</i> , "Immune Response to a Hepatitis B DNA Vaccine in Aotus Monkeys: A Comparison of Vaccine Formulation, Route, and Method of Administration," <i>Molec. Med.</i> 4:109-118, The Picower Institute Press (1998)
AS	AS	5	Gu, M.-L., <i>et al.</i> , "Protection against anthrax toxin by vaccination with a DNA plasmid encoding anthrax protective antigen," <i>Vaccine</i> 17:340-344, Elsevier Science Ltd. (1999)
AS	AT	5	Hammond, S.E. and Hanna, P.C., "Lethal Factor Active-Site Mutations Affect Catalytic Activity In Vitro," <i>Infection & Immunity</i> 66:2374-2378, American Society for Microbiology (1998)

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AS	AR	6	Hartikka, J., et al., "An Improved Plasmid DNA Expression Vector for Direct Injection into Skeletal Muscle," <i>Human Gene Ther.</i> 7:1205-1217, Mary Ann Liebert, Inc. (1996)				
AS	AS	6	Hartikka, J., et al., "Electroporation-Facilitated Delivery of Plasmid DNA in Skeletal Muscle: Plasmid Dependence of Muscle Damage and Effect of Poloxamer 188," <i>Molec. Ther.</i> 4:407-415, The American Society of Gene Therapy (November 2001)				
AS	AT	6	Henderson, D.W., "An Apparatus for the Study of Airborne Infection," <i>J. Hygiene</i> 50:53-68, Cambridge at the University Press (1952)				

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AS	AR	7	Holste, D., et al., "Optimization of Coding Potentials Using Positional Dependence of Nucleotide Frequencies," <i>J. Theor. Biol.</i> 206:525-537, Academic Press (2000)
AS	AS	7	Horn, N.A., et al., "Cancer Gene Therapy Using Plasmid DNA: Purification of DNA for Human Clinical Trials," <i>Human Gene Ther.</i> 6:565-573, Mary Ann Leibert, Inc., Publishers (1995)
AS	AT	7	Ivins, B.E. and Welkos, S.L., "Recent Advances in the Development of an Improved Human Anthrax Vaccine," <i>Eur. J. Epidemiol.</i> 4:12-19, Kluwer Academic Publishers (1988)

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	AM						Yes No
	AN						Yes No
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AS	AR	<u>8</u>	Ivins, B., et al., "Experimental anthrax vaccines: efficacy of adjuvants combined with protective antigen against an aerosol <i>Bacillus anthracis</i> spore challenge in guinea pigs," <i>Vaccine</i> 13:1779-1784, Elsevier Science Ltd. (1995)
AS	AS	<u>8</u>	Klmpel, K.R., et al., "Anthrax toxin protective antigen is activated by a cell surface protease with the sequence specificity and catalytic properties of furin," <i>Proc. Natl. Acad. Sci. USA</i> 89:10277-10281, National Academy of Sciences (1992)
AS	AT	<u>8</u>	Kobiler, D., et al., "Efficiency of Protection of Guinea Pigs against Infection with <i>Bacillus anthracis</i> Spores by Passive Immunization," <i>Infection & Immunity</i> 70:544-550, American Society for Microbiology (February 2002)

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AS	AR	9	Kushner, N., et al., "A fragment of anthrax lethal factor delivers proteins to the cytosol without requiring protective antigen," <i>Proc. Natl. Acad. Sci. USA</i> 100:6652-6657, National Academy of Sciences (May 2003)				
AS	AS	9	Leppia, S.H., "Anthrax toxin edema factor: A bacterial adenylate cyclase that increases cyclic AMP concentrations in eukaryotic cells," <i>Proc. Natl. Acad. Sci. USA</i> 79:3162-3266, National Academy of Sciences (1982)				
AS	AT	9	Leppia, S.H., "Production and Purification of Anthrax Toxin," <i>Meth. Enzymol.</i> 165:103-116, Academic Press, Inc. (1988)				

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AS	AR	10	Lindmayer, I., et al., "Development of New Jet Injector for Insulin Therapy," <i>Diabetes Care</i> 9:294-297, American Diabetes Association (1986)
AS	AS	10	Little, S.F. and Knudson, G.B., "Comparative Efficacy of <i>Bacillus anthracis</i> Live Spore Vaccine and Protective Antigen Vaccine against Anthrax in the Guinea Pig," <i>Infection & Immunity</i> 52:509-512, American Society for Microbiology (1986)
AS	AT	10	Manickan, E., et al., "DNA Vaccines - A Modern Gimmick or a Boon to Vaccinology?," <i>Crit. Rev. Immunol.</i> 17:139-154, Begell House, Inc. (1997)

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AS	AR	<u>11</u>	Martins, J. and Roedl, E.A., "Medijector - A New Method of Corticosteroid -Anesthetic Delivery," <i>J. Occup. Med.</i> 21:821-824, Williams and Wilkins (1979)				
AS	AS	<u>11</u>	McShane, H., "Prime-boost immunization strategies for infectious diseases," <i>Curr. Opin. Molec. Ther.</i> 4:23-27, PharmaPress Ltd. (February 2002)				
AS	AT	<u>11</u>	Mesnage, S. and Fouet, A., "Plasmid-Encoded Autolysin in <i>Bacillus anthracis</i> : Modular Structure and Catalytic Properties," <i>J. Bacteriol.</i> 184:331-334, American Society for Microbiology (January 2002)				

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AS	AR	<u>12</u>	Mikesell, P., et al., "Evidence for Plasmid-Mediated Toxin Production in <i>Bacillus anthracis</i> ," <i>Infection & Immunity</i> 39:371-376, American Society for Microbiology (1983)
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AS	AT	<u>12</u>	Mir, L.M., et al., "High-efficiency gene transfer into skeletal muscle mediated by electric pulses," <i>Proc. Natl. Acad. Sci. USA</i> 96:4262-4267, National Academy of Sciences (1999)

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		FIRST NAMED INVENTOR Hemanson, G.G.	
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AS	AS	<u>13</u>	Mock, M. and Fouet, A., "Anthrax," <i>Annu. Rev. Microbiol.</i> 55:647-671, Annual Reviews (January 2001)
AS	AT	<u>13</u>	Nagata, T., et al., "Codon Optimization Effect on Translational Efficiency of DNA Vaccine in Mammalian Cells: Analysis of Plasmid DNA Encoding a CTL Epitope Derived from Microorganisms," <i>Biochem. Biophys. Res. Commun.</i> 261:445-451, Academic Press (1999)

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AS	AR	<u>15</u>	Osorio, J.E., <i>et al.</i> , "Immunization of dogs and cats with a DNA vaccine against rabies virus," <i>Vaccine</i> 17:1109-1116, Elsevier Science Ltd. (1999)
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AS	AR	<u>17</u>	Pitt, M.L.M., <i>et al.</i> , "In vitro correlate of immunity in a rabbit model of inhalational anthrax," <i>Vaccine</i> 19:4768-4773, Elsevier Science Ltd. (September 2001)
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AS	AT	<u>19</u>	Schrijver, R.S., et al., "Immunization of cattle with a BHV1 vector vaccine or a DNA vaccine both coding for the G protein of BRSV," <i>Vaccine</i> 15:1908-1916, Elsevier Science Ltd. (1997)

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AS	AR	<u>20</u>	Shiver, J.W., et al., "Replication-incompetent adenoviral vaccine vector elicits effective anti-immunodeficiency-virus immunity," <i>Nature</i> 415:331-335, Nature Publishing Company (January 2002)
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EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL						Yes
	AM						No
	AN						Yes
	AO						No
	AP						Yes
							No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

AS	AR	<u>26</u>	NCBI Entrez, GenBank Report, Accession No. AAA22637, Welkos, S.L., et al., (Entry date 1999)
AS	AS	<u>26</u>	NCBI Entrez, GenBank Report, Accession No. M22589, Welkos, S., (Entry date 1999)
AS	AT	<u>26</u>	NCBI Entrez, GenBank Report, Accession No. AAA22569, Lowe, J., (Entry date 1993)

EXAMINER <u>/Anoop Singh/</u>	DATE CONSIDERED 04/28/2006
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FORM PTO-1449 <u>INFORMATION DISCLOSURE STATEMENT</u>		ATTY. DOCKET NO. 1530.0460002/EJH/JAH	APPLICATION NO. 10/658,688
		FIRST NAMED INVENTOR Hermanson, G.G.	
		FILING DATE September 10, 2003	ART UNIT 1632

U.S. PATENT DOCUMENTS

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	AN						Yes
	AO						No
	AP						Yes
							No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

AS	AR	<u>27</u>	File 351, Accession No. 8246987, Derwent WPI English language abstract for CA 2,001,508 (Document AL1), EP 0 366 550 A1 (Document AM1), and WO 90/04637 (Document AN1)
AS	AS	<u>27</u>	STNEasy Database, Accession No. 2001:208128, English language abstract for WO 2001019395 A1 (Document No. AN3)
AS	AT	<u>27</u>	Copy of Co-Pending U.S. Patent Application No. 10/748,853 (unpublished), inventor Wheeler, C.J., filed December 30, 2003

EXAMINER <i>/Anoop Singh/</i>	DATE CONSIDERED 04/28/2006
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	AN						Yes
	AO						No
	AP						Yes
							No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

AS	AR	<u>28</u>	Copy of Co-Pending U.S. Patent Application No. 08/486,533 (unpublished), inventors Felgner et al., filed June 07, 1995.
	AS	<u>28</u>	
	AT	<u>28</u>	

EXAMINER	/Anoop Singh/	DATE CONSIDERED	04/28/2006
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Substitute for form 1449/PTO

**FIRST SUPPLEMENTAL
INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Sheet 1 of 1

<p>Substitute for form 1449/PTO</p> <p>FIRST SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT BY APPLICANT</p> <p><i>(Use as many sheets as necessary)</i></p>	Complete if Known		
	Application Number	10/658,688	
	Filing Date	September 10, 2003	
	First Named Inventor	Gary Hermanson	
	Art Unit	1645	
	Examiner Name	Baskar, P.	
Sheet	1	of	1
		Attorney Docket Number	1530.0460002/EJH/J-H

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Examiner Signature	/Anoop Singh/	Date Considered	04/28/2006
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Substitute for form 1449/PTO				Complete if Known	
				Application Number	10/658,688
				Filing Date	September 10, 2003
				First Named Inventor	Hermanson
				Art Unit	1645
				Examiner Name	Baskar, P.
Sheet 1 of 1		Attorney Docket Number 1530.0460002/EJH/J-H			

NON PATENT LITERATURE DOCUMENTS						
Examiner Initials*	Cite No. ¹	Include name of the author, title of the article, title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume number, publisher				T ²
AS	NPL1	Okinaka, R.T., <i>et al.</i> , "Sequence and Organization of pXO1, the Large <i>Bacillus anthracis</i> Plasmid Harboring the Anthrax Toxin Genes," <i>J. Bacteriol.</i> 181:6509-6515, American Society for Microbiology (1999)				
AS	NPL2	Price, L.B., <i>et al.</i> , "Genetic Diversity in the Protective Antigen Gene of <i>Bacillus anthracis</i> ," <i>J. Bacteriol.</i> 181:2358-2362, American Society for Microbiology (1999)				
AS	NPL3	Co-pending U.S. Patent Application No. 10/843,656, inventors Vilalta, A., <i>et al.</i> , filed May 12, 2004 (NOT PUBLISHED)				
AS	NPL4	Hermanson, G., <i>et al.</i> , "A Cationic Lipid-Formulated Plasmid DNA Vaccine Confers Sustained Antibody-Mediated Protection Against Aerosolized Anthrax Spores," <i>Proc. Natl. Acad. Sci. USA</i> 101:13601-13606, National Academy of Sciences (2004)				

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Examiner Signature	/Anoop Singh/	Date Considered	04/28/2006
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